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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,720	09/29/2006	Isamu Koyama	740819-1160	9395
78198	7590	12/08/2009		
Studebaker & Brackett PC One Fountain Square 11911 Freedom Drive, Suite 750 Reston, VA 20190			EXAMINER SZPRA, JULIE ANN	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 12/08/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/594,720

Applicant(s)

KOYAMA ET AL.

Examiner

JULIE A. SZPIRA

Art Unit

3731

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-7 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 2, 4-7 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicant's amendment filed 8/12/2009.

Claims 1, 2, 4-7 and 10 are pending and an action on the merits is as follows.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1, 2, 4-7 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Fukuda et al. (US 3,871,358)** in view of **Turnbull (US 5,996,582)** further in view of **Gomez (US 6,053,166)**.

Regarding claims 1 and 2, Fukuda et al. discloses a tubular member (4) having an inner passageway (1a) between its opposite ends, a reinforcement member (3) formed by a plate extending along a perimeter of the inner passageway, wherein the tubular member and reinforcement element have curved (flexible) shapes (Figure 3, element 1) and is conformable (has the ability to conform; flexible) to the shape of a

pharynx of a human body (column 1, lines 37-41), but fails to disclose a the guiding member and tubular member having engagement sections.

However, Turnbull teaches a guide member (shield, 20) with an engagement section (stop, 22), and a tubular member (10), with an engagement section (machine end, 13) for engaging with the guide member engagement section when the guide member is inserted up to a predetermined portion in the inner passageway of the tubular member (column 2, lines 50-56).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include engagement sections to limit the extent of insertion of the guide member in the tubular member (column 2, lines 51-53).

Fukuda et al. in view of Turnbull discloses the invention as above, but fails to disclose the guiding member and tubular member having alignment marks.

However, Gomez teaches an alignment marks (introduction segments; 22, 26, 30) coupled to the guiding member and tubular member to align (curve) both of the members (column 7, lines 60-64).

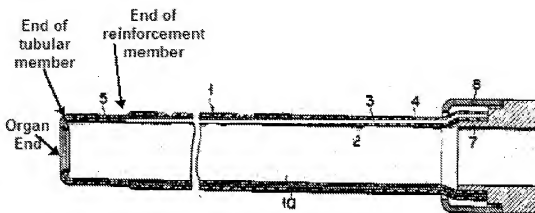
It would have been obvious to one having ordinary skill in the art at the time the invention was made to include alignment elements so the guiding member and the tubular member achieve the correct position for accurate deployment in the patient (column 8, lines 17-24).

The limitation "when guiding to the pharynx and retained there..." has not been given patentable weight, as it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the

claimed apparatus from a prior art apparatus satisfying the claimed structural limitations.
Ex Parte Masham, 2 USPQ F.2d 1647.

Regarding claim 4, Fukuda et al. discloses the reinforcement member has the shape of a spiral (helical) continuously extending in a center line direction of the inner passageway (column 2, lines 6-9).

Regarding claim 5, Fukuda et al. discloses wherein a digestive organ end of the tubular member extend toward a digestive organ ahead of a digestive organ end of the reinforcement member (column 2, lines 14-20).



Regarding claim 10, Fukuda et al. discloses the tubular member being made of a resin material (column 2, lines 1-2), but fails to disclose a guiding member made of another resin material harder than the material of the tubular member.

However, Turnbull discloses a stiff rod guiding member made of fiberglass (which is known to contain a resin) (column 2, lines 50-54).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the guiding member out of a harder resin since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

4. Applicant's arguments filed 8/12/2009 have been fully considered but they are not persuasive.
5. In response to applicant's argument that the guiding member and alignment members disclosed by Turnbull and Gomez do not perform the claimed tasks, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The guiding member disclosed by Turnbull has the structural ability to engage a tubular engagement section, and whether or not the engagement occurs at a certain point of insertion is not germane to the patentability of the device. The Turnbull guiding

member can perform the claimed task, and it would have been obvious to one having ordinary skill in the art to adjust the guiding member to perform a specific function.

The alignment member disclosed by Gomez also has the structural ability to be engaged with a tubular member alignment mark when a digestive organ end of the guiding member is generally coincident with a digestive organ end of the tubular member, and when the structure is apparent, the intended use does not differentiate the present application from prior art.

How the members are "aligned" or "engaged" is not fully defined in a way to differentiate the present invention from the prior art. Without further description to define how the members are aligned (longitudinally, radially, laterally), any user defined plane can be seen as the members being "aligned". "Aligned" has a meaning of "place in a line", and any line which the alignment members fall upon would be considered "alignment" of those members. While it is understood that the present invention differs from the prior art of record, the claim language of the present invention is not distinct enough to allow patentability. The present application discloses how the alignment marks are to be aligned in paragraphs 102 to 109 and Figure 18, and limitations describing that alignment from the specification should be included in the claims.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie A Szpiral/
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
12/7/09